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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--------------------------------------|----------------|----------------------|-------------------------|-----------------|
| 10/661,139 | 09/12/2003 | Jagadish C. Sircar | AVANIR.111A | 7736 |
| 20995 7 | 590 03/01/2006 | EXAM | | INER |
| KNOBBE MARTENS OLSON & BEAR LLP | | | SHAMEEM, GOLAM M | |
| 2040 MAIN STREET FOURTEENTH FLOOR | | ART UNIT | PAPER NUMBER | |
| IRVINE, CA 92614 | | | 1626 | |
| | | | DATE MAILED: 03/01/2006 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|--|--|---|--|--|--|--|
| Office Action Summary | | 10/661,139 | SIRCAR ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Golam M. M. Shameem, Ph.D. | 1626 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| WHIC - External after - If NO - Failu Any | ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D assions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailine and patent term adjustment. See 37 CFR 1.704(b). | PATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 11 January 2006. | | | | | | |
| | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | |
| 3)[| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | ion of Claims | | | | | | |
| 4)🖂 | 4)⊠ Claim(s) <u>1-41</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) 13-33 is/are withdrawn from consideration. | | | | | | |
| 5)□ | Claim(s) is/are allowed. | | | | | | |
| 6)⊠ | Claim(s) 4,7,9 and 11 is/are rejected. | | | | | | |
| 7)⊠ | Claim(s) <u>1-3,5,6,8,10,12 and 34-41</u> is/are objected to. | | | | | | |
| 8)□ | 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicati | on Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| | Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachmen | R(s) | | • | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) | | | | | | | |
| | r No(s)/Mail Date <u>06/15/2004</u> . | 6) Other: | | | | | |

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DETAILED ACTION

Priority

This application claims benefit for domestic priority under 35 U.S.C. § 119(e) [to a provisional application 60/410,777 09/12/2002], is acknowledged.

Status of Claims

Claims 1-41 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on January 11, 2006 and that has been entered. Claims 1 and 4-12 have been amended.

Claims 13-33 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 06/15/2004 and 05/18/2004, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, (which includes claims 1-12 and 34-41 drawn to compounds and their methods of making and the elected species as set forth found in Compound S-97 (Remarks, page 42) without traverse is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, and therefore, the requirement for restriction is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

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As set forth in the restriction requirement and an election of a single compound (or set of compounds), the invention will encompass all compounds in claim 1 [(Genus I, II, III and IV only), and Genus V-VIII are withdrawn] that fall within the scope of the claim is as follows:

A compound having the formula as shown in claim 1 [Genus I, II, III and IV only)] wherein:

R₁ is as limited to Nitrogen containing 6-membered ring,

R₂ is as claimed,

L and M are as claimed and

R is as defined except hydrogen.

As a result of the election and the corresponding scope of the compound identified, claims 13-33 and the remaining subject matter of claims 1-12 and 34-41 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 13-33 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claim in the subject matter, which the applicant regards as his invention.

Claims 4, 7, 9 and 11 are rejected under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "compound comprising" (recited in line 1

for each of above claims) renders the claims indefinite because it is unclear from the claims what the Applicant is intending to encompass with the expression "compound comprising". The word "comprising" is an open-ended word that, when used with a product (which is a compound) within a claim, make the claim open-ended and indefinite and therefore, it is not possible to ascertain the metes and bounds of the claimed subject matter. The omission of failing to describe the claimed invention renders the claim incomplete. It is suggested to amend the claim with in the context and scope of the claim in order to overcome the rejection. Appropriate correction is required.

Objections

Claims 1-12 and 34-41 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (571)-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft

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documents and other communications with the PTO that are not for entry into the file of the

application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35

U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be

addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of

record in the application file. PTO employees will not communicate with applicant via Internet

e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

data could be identified unless there is of record an express waiver of the confidentiality

requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG

89.

Any inquiry of a general nature or relating to the status of this application should be

directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M M Shameem, Ph.D. **Primary Examiner** Art Unit 1626

Technology Center 1600

GOLAM M. M. SHAMEEM, PH.D PRIMARY EXAMINER

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February 20, 2006